Atty. Dkt. No. 081356-0162

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Katsuhiko Mikoshiba *et al.*

Title: RNA-BINDING PROTEIN

Appl. No.: 09/821,687 Filing Date: 03/30/2001

Examiner: Konstantina T. Katcheves Art Unit: 1636

PETITION TO THE GROUP ART DIRECTOR

Group Director
Art Unit 1600
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicants hereby petition the Group Director of Art Unit 1600 under 37 C.F.R. §1.181 for the examination of all pending claims. Under 37 C.F.R. §1.181(f), this petition is being filed on a timely basis, within two months of the mailing date of the Office Action dated May 7, 2003.

Action Requested

In accordance with MPEP §803.04 and the Commissioner's Notice on Examination of Patent Applications Containing Nucleotide Sequences, 1232 *OG* 242 (116), applicants petition for the examination of the polynucleotide sequences of claims 3-6. Applicants also request the examination of the peptide sequences of claims 1 and 2, along with examination of Groups I-VI.

Statement of Facts

1. The Examiner issued a restriction requirement, dividing the inventions into Groups I-VI and further dividing the invention into SEQ ID NOs: 1 and 2. See paper number 10, dated October 1, 2002.

Group I, claims 1 and 2, is drawn to an isolated peptide. Group II, claims 3-8 and 21-23, is drawn to an isolated gene. Group III, claim 9, is drawn to a method of producing and isolating an RNA-binding protein. Group IV, claims 10 and 24, is drawn to an antibody. Group V, claims 11-14, and 25-32, is drawn to a pharmaceutical composition or therapeutic

use. Group VI, claims 15-20 and 33-36, is drawn to a reagent for detecting a Synaptotgmin-binding protein and RNA binding protein and a method for detecting Synaptotgmin.

SEQ ID NOs: 1 and 2 were subject to further restriction requirement.

2. Applicants responded on February 13, 2003 by electing Group II.

3. The Examiner issued an Office Communication (paper number 12) dated January 14, 2003, stating that the applicants' response was non-responsive for failure to elect only one sequence for examination.

4. Applicants responded by electing with traverse SEQ ID NO: 3 in the response dated February 14, 2003.

6. The Examiner then issued an Office Action dated May 7, 2003 informing applicants that the restriction requirement was final but that the nucleic acid sequence encoded by SEQ ID NO: 4 was examined as well, along with the elected nucleic acid SEQ ID NO: 3, as a courtesy.

Argument

Limiting Applicants to One Polynucleotide Sequence Instead of Up to Ten Sequences

The Examiner's restriction, requiring a separate application for each polynucleotide, is in violation of MPEP §803.04, which states that "normally ten sequences constitute a reasonable number for examination purposes." This is true even if each nucleotide sequence is an independent and distinct invention under 35 USC §121. The Commissioner has decided *sua sponte* to waive the requirements of 37 CFR §1.141 *et seq.* and to permit the claiming of a reasonable number of nucleotide sequences in an application, thereby to "aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office." Applicants urge that, in these times of scarce capital and deflated stock prices for biotechnology companies, the Commissioner's Notice is even more apropos than it in March of 2000.

The Examiner also has not demonstrated "a serious burden," because the nucleic acid sequences of SEQ ID NO: 1-4 are readily considered together. Indeed, the Examiner already has examined the coding polynucleotide SEQ ID NO: 3 (i.e., claim 6) and its respective degenerate polynucleotide genus (the encoding polynucleotides of SEQ ID NO: 4, recited in claim 4). That is, the Examiner has examined the polynucleotide sequences of claims 4 and 6,

which correspond to the full length peptide of claim. Accordingly, it would not be a serious burden for the Examiner also to examine the remaining, partial nucleotide sequences. The latter are prescribed in claims 3 and 5, which respectively relate to the degenerate polynucleotide sequences encoding amino acid SEQ ID NO: 2 and the polynucleotide sequence corresponding to amino acid SEQ ID NO: 2.

Even if the Examiner's position is that the burden to examine the sequences of claims 3-6 is high, applicants contend that they are entitled, under MPEP §803.04 and the Commissioner's Notice of all nucleotide sequences related to these claims. Both the MPEP and the Notice state that "normally ten sequences constitute a reasonable number." These authorities also state that, in "some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence recited three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten (10)." The Examiner has proffered no reason as to why the polynucleotide sequences of claims 3-6 is an exceptional circumstance that necessitates deviation from the normal practice of the MPEP and the Commissioner's Notice.

Restricting Groups I or II from Groups III -VI

The Examiner has not established a *prima facie* case that the restriction is proper. As Section 803 of the MPEP states:

> an application may properly be restricted to one of two or more inventions only if they are able to support separate patents and they are either independent or distinct. If the search of the entire application can be made without serious burden, the examiner **must** examine it on the merits, **even though** it includes claims to independent or distinct inventions....There are two criteria for a proper requirement for restriction between two patentably distinct inventions: (A) The inventions must be independent or distinct as claimed; **and** (B) There must be a serious burden on the examiner if restriction is required.

(Emphasis added; citations omitted.) From this perspective, the Examiner has not offered sufficient evidence to demonstrate either parts (A) or (B) with respect to examining Groups I and III-VI as they relate to or depend from Group II, the polynucleotides.

Group I

In restricting Group I from the other claims, the Examiner stated that the present claims are to unrelated inventions. Inventions are unrelated "where they are not connected in design, operation, or effect under the disclosure of the particular application under consideration." MPEP §808.01, at 800-38. This section of the MPEP gives an example of unrelated inventions as "a necktie and a locomotive bearing." In the instant case, all of the restricted Groups relate to Synaptotgmin proteins of Group I. Group II relates to the polynucleotides that encode these proteins. Group III is a method of producing these related polynucleotides. Group II is drawn to antibodies against the proteins of Group I. Group V recites pharmaceutical compositions or therapeutic agents comprising the claimed peptides or polynucleotides. Groups VI relates to using the proteins of Group I to detect binding proteins. Accordingly, the restriction is improper because all of the claims of Groups I-VI are related.

Group VI

The restriction of Group VI and Groups I and IV is improper because these inventions are related. Group VI is drawn to reagents or methods for detecting a Synaptotgmin binding protein using antibodies of Group IV, raised against the proteins of Group I. Therefore, Group VI is connected in design, operation and effect to both Groups I and IV and restriction is improper.

Groups I or II from Groups IV-VI

Furthermore, the restriction of Groups I or II from Groups IV-VI is an improper combination-subcombination restriction. Section of the MPEP 806.05(c) at page 800-34 states that "in order to establish that combination and subcombination inventions are distinct, two-way distinctness must be provided." If the invention falls under Subsection II, where the subcombination is essential to the patentability of the combination, then "restriction must not be made" (emphasis added).

Group IV

The claims of Group IV are directed to an antibody, which would not be patentable per se but for the recitations of the amino acids of Group I of the present invention. As the Examiner cannot establish two-way distinctness, restriction therefore is improper between Group I and Group IV.

Group V

The restriction of Group V from Groups I and II likewise is improper. The claims of Group V are not patentable per se but for the recitations of the polynucleotide of Group II or the amino acid of Group I of the present invention.

Group III

The restriction of Group III (claim 9) from Group II is improper under the *Ochiai* guidelines. Claim 9 is drawn to a method of producing a polynucleotide of Group II. As a result of the *Ochiai* decision, applicants are entitled to have method claims rejoined if the polynucleotides are found to be patentable. If the Examiner will not examine at least claim 9 presently, then applicants will seek rejoinder upon the finding of allowable subject matter.

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If any additional fees and/or extension(s) of time are required for the filing of this paper, counsel expressly petitions for such extension(s) and authorizes the Commissioner to charge any further fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date July 7, 2003

By _____

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